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1) Summary of policy proposals:

OPO Metrics and Accountability

- Accelerate the implementation date for the final rule so that all parts of the country can be served by high performing OPOs as soon as possible;
- Update definition of "Urgent Need" to allow for decertifications of OPOs, defining urgent need as "occur[ing] when an OPO's non-compliance with one or more conditions for coverage has caused, or is likely to cause, serious injury, harm, impairment, or death to a potential or actual donor or a potential or actual organ recipient, or inferior service to any racial or ethnic group(s), as defined by variable rates of service at any point in the OPO's process data."
- Update OPO Conditions for Coverage in line with recommendations offered by alumni of the United States Digital Service.
- Reject OPO calls to lower standards of service for minority patient populations via a "race-based adjustment", which Congresswoman Ayanna Pressley characterized as a "racist request", and which past NAACP President Ben Jealous argued would "codify inequity into the health care system".
    - Research shows unequivocally that lower donation rates about minority patient populations result from inferior and racially-biased services they receive from OPOs, and a race-based adjustment would only remove all regulatory pressure from OPOs to begin to provide more equitable service.
- Reject calls from OPOs to credit them to zero donors, given that such a metric would be extremely gameable, and AOPO has already formally admitted that OPOs game metrics and exploit loopholes in order to gain recertification, even when it comes directly at the expense of saving patients lives.

- Close the pancreata for research loophole, which OPOs have already begun to exploit.
    - The 2019 NPRM took a seemingly unintentional divergence from the 2006 rule, by interpreting Pancreatic Islet Cell Transplantation Act of 2004 which amended the PHSA to include all pancreata for research, instead of the narrower/more appropriate pancreata islet cells. CMS should revert back to the more narrow definition, in line with original Congressional intent.

OPO Transparency

- Enable accountability and iterative research-informed policymaking by publishing OPO process data publicly, in line with international best practice standards for OPO transparency.
    - In addition to meeting with international standards, 7 U.S.-based OPOs have already committed to sharing such data voluntarily, noting that "*this is data which can be easily and readily shared by all OPOs.*"

Criteria for Competition for OPO DSAs

- Follow the detailed guidance for seamless and patient-centric decertifications of Tier 2 and 3 OPOs as published by the Bridgespan Group, with public endorsement from two past AOPO presidents.
    - Importantly, counter to baseless and fearmongering lobbying from AOPO, there have been 71 OPO mergers in history, and never once has it resulted in any "system disruption." CMS should not hesitate to take every opportunity to scale the service areas of higher-performing OPOs.
- In criteria for competition for DSAs:
    - Prioritize lives saved through OPO performance metrics (donation and transplantation rate) as well as (1) evidence of equitable treatment for all patients, including as defined as similar rates of service across racial and ethnic patient groups across all process data metrics (e.g., timely response rates to donor referrals); and (2) demonstrated capabilities and systems for data and logistics management;
    - Mandate that any OPO whose territory is up for competition (i.e., Tiers 2 and 3 OPOs) publish data pertaining to its procurement operations, finances, hospital relationships, and staff and governance in order to empower acquiring OPOs to submit more informed bid proposals and, related, to allow CMS to better assess the likelihood of success of each bid.

Governance and Oversight

- Create an empowered and deconflicted Office of Organ Policy to streamline policymaking, as supported by the House Appropriations Committee, then-Chair of the Congressional Black Caucus Karen Bass, Nobel Laureate Al Roth, past NAACP President Ben Jealous, and all 5 past bipartisan HHS Chief Technology Officers, among other Congressional leaders and patient groups.
- Reabsorb oversight responsibilities from the OPTN, given that its current contractor UNOS is under bipartisan investigation from the Senate Finance Committee for conflicts

of interest and OPO protectionism, and now even states that no longer believes that its role is even to provide oversight at all; and
- Mandate conflicts of interest disclosures for all OPO executives and board members, including related to tissue donation, and disallow compensation for OPO board service.

Reform OPO reimbursement structure
- Change the current regulation governing payments to OPOs (42 CFR 413.200) with a reformed financing mechanism that is fair and transparent and provides incentives to drive higher volumes of organ procurement, helping more patients access transplants, and reducing conflicts of interest and industry protectionism.
    - Alternatively, CMS can use its waiver authority under Section 1115A of the Social Security Act to design and launch a demonstration project (via the Center for Medicare & Medicaid Innovation) to test alternative methods of reimbursement, just as it has done in a variety of areas, such as the mandatory comprehensive joint replacement program which has successfully lowered costs.

Technology
- Support any efforts by HHS, in all possible ways, to make the OPTN contract more competitive, including because UNOS's technology serves as a rate-limiting factor that stifles all innovation in the industry, including OPO technology;
- Separate organ transportation and tracking into their own federal contract(s), given the severe failures of many OPOs and the OPTN to perform such functions;
- Incentivize technology innovation at OPOs by considering an OPO's technological and logistics management capability in CMS's criteria for competition for an OPO service area, especially considering that such capabilities will be of even greater importance as an OPO increases the size of the geography it covers and the workforce it manages through expansion. Specifically, CMS can define such capabilities as: (1) Ability to interface with Hospitals electronically using APIs; (2) Ability to use automation and ML/AI to improve outcomes; (3) Ability to respond in a timely manner to Reporting requirements; and (4) Desire to innovate and improve Digital Services.
- CMS should coordinate with the Office of the National Coordinator (ONC) to identify and address all barriers to building and implementing scalable platforms for integrating OPO technology systems with EMR, including to enable automated donor referrals.

2. Organize Overview

Organize, a non-profit patient advocacy organization which served as "Innovator in Residence" in the Office of the Secretary of the U.S. Department of Health and Human Services (HHS) under the Obama-Biden Administration, appreciates the opportunity to comment on CMS's "Request for Information; Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities."

Before beginning with recommendations for system reform, as the founder and CEO of Organize, I want to clarify misinformation which I understand some OPOs have actively

disseminated in an attempt to undermine patient-centered policy recommendations, including much-needed accountability for OPOs and competition of the OPTN.

I come to the issue of OPO accountability via a personal connection. My father waited 5 years for a heart transplant, enduring 3 open-heart surgeries in the process, and almost dying many times. The most difficult day of my life was when he called me to say goodbye, sure at the time he would not survive the night. Nine months after my father's transplant, one of his sisters (my aunt) also received a heart transplant, and ten years later, another of their sisters died in need of a heart transplant.

Through this process, our family learned that we suffer from a genetic mutation, and I have learned that four other of my close relatives will need heart transplants in the future as well. I have since left my previous profession and made patient advocacy my life's work. Research has shown that America can eliminate the waiting list for heart transplants entirely through basic, common sense accountability and reform to OPOs, and I am committed to doing everything I can do, for as long as it takes, to realize this opportunity to save the lives of my family members.

When I first launched Organize, we consulted with many OPO leaders who led us to believe that the biggest problem at the time was a frictionful donor registration process. We have subsequently learned that this is far from the biggest problem, but we were, at the time, following guidance from OPO stakeholders, because at the time we naively believed all OPOs operated in good faith. Following such guidance, we built and launched a donor registration platform, in consultation with Blair and Fred Sadler, the original authors of the Uniform Anatomical Gift Act, and in compliance with all State and Federal laws.

Additionally, we focused on creating a more empathetic and human centered next of kin experience, allowing next of kin - should they want it - the opportunity to view expressions of their loved one's organ donation wishes posted publicly on social media, for which we won the Inaugural Health Care Design Award from Stanford MedX. This was meant to increase trust in the registration process and decrease instances of post traumatic stress disorder among donor families by enabling a more human-centered experience.

After gaining initial traction, Donate Life America encouraged us to operate as a for-profit company so that we would not be competitive with them, with a potential strategy of licensing software to OPOs (as is standard in the OPO industry) as well as providing marketing services to OPOs and, when relevant, responding to government RFPs for organ donation marketing campaigns (as is also standard in the OPO industry). Per their guidance, we explored this option, though never actualized it in any way as we ultimately concluded that our efforts were better spent pursuing policy reforms to address the now-well documented problems with OPOs and the OPTN, which are the real root problems preventing patients from accessing lifesaving transplants: lack of accountability for terrible performance, near-complete opacity, and unchecked conflicts of interest.

Organize is a non-profit organization, singly focused on improving patient outcomes through commonsense OPO accountability, as supported by every major patient group engaged on this issue. Neither we nor our non-profit funders have, or have ever had, any conflicts of interest or any financial motivations, as certified by HHS in advance of awarding us an Innovator in Residence position in the Office of the HHS Secretary.

OPOs certainly seem to recognize this, as now the claims are made through a wildly offensive astroturf campaign called "Science in Donation", which the Project on Government Oversight reported is run by the New Jersey Sharing Network OPO - whose CEO, Joe Roth, has served as a member of the AOPO Legislative and Regulatory Affairs Committee - suggesting that AOPO and the OPO community know better than to make the claims themselves, given that they are abjectly false, defamatory, and anti-Semitic.

We also note that the New Jersey Sharing Network's General Counsel, Christina Strong, was covered by the LA Times in investigative reporting about efforts by another of her clients, OneLegacy, to obstruct the LA Times's investigation into the OPO's illicit and unethical relationships with for-profit tissue processors.

I, like most people in the organ donation industry, often hear about how important public trust is to ensuring a functioning organ donation system. The logical extension of that, of course, is how important it should be for CMS to ensure that its organ donation contractors are worthy of public trust and the reforms offered in the RFI response below would constitute much-needed steps toward that goal. We hope CMS implements them on behalf of patients.

3. Context on recent OPO performance: the U.S. is NOT the best organ donation system in the world

Counter to the industry lobbying narrative of the U.S. organ donation system being the "best in the world" and enjoying successive years of "record growth", there is a tremendous opportunity and an urgent need to address severe deficiencies in the organ procurement system, the failures of which disproportionately impact patients of color.

A data-driven assessment of the system finds that: "*it is indisputable that nationally the increased number of donors is almost wholly attributable to the drug epidemic, and reflects the byproduct of a national tragedy, rather than an improved system to be celebrated*."

In fact, peer-reviewed research shows that, after controlling for increases in donation due to factors outside of OPOs' control (e.g., increases in opioid deaths, gun deaths, expansion of the donor poor due to transplant center innovation, and population growth), OPOs have actually gotten worse over this same period for which they self-celebrate their "success" (see here for data visualization).

Similarly, the common OPO refrain that the American organ donation system is the "best in the world" misunderstands what the data actually show. While the U.S. now has the highest number

of organ *donors per capita* of any country, this completely ignores that the U.S. has significantly higher rates of the kinds of deaths which allow for organ donation to occur.

Specifically, on a per capita basis among wealthy nations, the U.S. has 20-30 times more opioid deaths, 25 times as many gun deaths, the highest suicides rates, and more than twice as many fatal car accidents, which new data show spiked again last year during the pandemic.

The data-driven reality is that the U.S. has more organ donors per capita than other countries because we have higher levels of societal tragedies. After controlling for these differences, despite having excellent transplant surgeons, the U.S. system is middling at best. Framing this as a success of the system not only misunderstands the drivers of the U.S.'s higher per capita donation rates, but it dishonors the donors who suffered from the societal tragedies that caused their deaths, and risks crowding out much-needed reforms to help patients who need transplants now and in the future, and likely would not receive them absent meaning OPO and OPTN reforms.

Perhaps even more troublingly, the fact that UNOS and OPOs do not seem to understand the drivers of donation, or even how to describe procurement practice in the US, calls into question their ability to identify and rectify system failures, and further underscores the need for additional data transparency and enhanced governance and oversight, themes which will animate many of our policy suggestions offered below.

4. Addressing Health Disparities

Questions addressed:

How can those in the transplant ecosystem better educate and connect with these communities about organ donation, so as to address the role that institutional mistrust plays in consenting to organ donation?

Are there revisions that can be made to the transplant program CoPs or the OPO CfCs to reduce disparities in organ transplantation?

Further, are there ways that transplant programs or OPOs could or should consider social determinants of health in their policies, such as those relating to requesting consent for donation, patient and living donor selection, or patient and living donor rights?

We greatly appreciate CMS's focus on disparities in the current transplant system. It is also important to understand that these disparities result from compounding inefficiencies and failures throughout the OPO system, rather than any one acute issue. As such, the solutions, too, will build on the broader themes of OPO accountability and transparency forwarded by CMS in the 2020 OPO final rule.

Related, we want to again laud CMS for prioritizing patients in the final rule, in line with support from every major patient group engaged in the rulemaking process. Related, we highlight that the rule itself already makes a major step forward in the goal of addressing inequity; as Ben Jealous, past president of the NAACP, has written in support of CMS's rule: "*An OPO's underperformance is often a very close proxy for its disparate treatment of communities of color. By moving to an objective standard for evaluating OPOs, however, OPOs can no longer [by virtue of the OPO final rule] choose—without consequence—not to approach certain families. As a practical matter, OPOs will have an incentive to invest more heavily in building relationships with hospitals that serve minority populations and in hiring a more diverse workforce."*

To that end, we want to specifically commend CMS on rejecting the OPO lobbying request for a "race-based adjustment" - which Congresswoman Ayanna Pressley characterized as a "racist request", and which Ben Jealous argued would "codify inequity into the health care system" - as it would allow OPOs to continue to ignore and otherwise deprioritize service for patients of color, and would only serve to perpetuate the very disparities we should all want to rectify.

As UNOS CEO Brian Shepard wrote of the system that only UNOS has ever overseen (while also lobbying against reforms championed by equity leaders such as Ben Jealous and then-Chair of the Congressional Black Caucus Karen Bass): *"Only people who have means can get transplants"...* and that the only real decision is whether or not UNOS should "*give transplants to [the rich people] who have to live near poor people.*" This marries with a wealth of data showing systematic disparities for - and discrimination against - patients of color.

For example, as highlighted in a report from alumni of the U.S. Digital Service cataloging peer-reviewed research into such disparities, *"The organ donation system is failing patients and donor families of color through every phase of the process – from getting on the waitlist, to finding a match, to becoming a donor. Both donor families and patients of color who need an organ experience different treatments and a system deeply rooted in inequity."*

However, while many in the OPO industry often blame communities of color for lower donation rates - suggesting that such rates result from lower levels of generosity in those communities and/or 'mistrust of the system' - the data clearly show that the disparities result from the inferior service and procurement clinical care OPOs provide these communities. As Ben Jealous wrote, *"Black families' experiences can be tied directly to OPO management choices, including hiring predominantly White work forces, and seemingly being unwilling or unable to adopt culturally competent practices."*

For example, peer-reviewed research finds that OPOs are only half as likely to even respond to a referral involving a Black versus a white donor and provide Black families with "less complete discussions about the possibility of organ donation", including spending."

This marries with additional research comparing the experience of Black families who consent to donation versus decline to donate, which found that among the biggest reasons Black families

decline donation is that the OPO did not *"give [them] enough time to discuss important issues… or respond to strong emotion with sensitivity and empathy."*

Clearly, the interpersonal treatment of families of color and the quality of procurement clinical care provided to donors of color are factors, and are squarely within the purview and control of the OPO. In fact, analysis of OPO data published by CMS reveal a 10-fold variability in OPO service of Black communities, often with stark variability across DSA boundary lines (comparing Mid-America Transplant and Arkansas Regional Organ Recovery Agency, for example) which would seem to be entirely unexplained by patient population, or any factor other than OPO performance.

This is further reinforced by a recent OPO turnaround in San Francisco. After years of dismal performance, especially among minority patient populations, the OPO (Donor Network West) hired the first Black OPO CEO in the country, who took an active approach toward treating the entire community more equitably and inclusively. Within just one year, organ procurement rates among Black donors increased by 70%, and organ procurement rates among Asian donors increased by 95%, further suggesting that minority patient procurement rates are far more a function of OPO operations than cultural factors or mistrust within those communities.

As such, it is vital that any policy solutions forwarded by CMS center the differential OPO communication practices with and clinical care provided to patients of color, rather than to focus solutions on increased education and outreach, which subtly shifts blame to those marginalized communities for the inferior and often racially-biased provision of services they receive from federal contractors. Rather, CMS should take steps to help ensure that OPOs show up to all potential donor cases in a timely way, and otherwise treat all donor families compassionately and fairly, which is where research suggests the biggest opportunities to achieve equity lie.

To that end, the most effective and implementable policy solutions are two-fold. The first is for CMS to enforce the recent OPO rule as soon as possible, ensuring that all parts of the country are served by high-performing OPOs, even in advance of 2026 (more on this point below in the section regarding the "Anticipated outcomes of OPO consolidation or expansion").

The second is to make all OPO process data publicly available, which will enable transparency and research into such differential OPO communications with donor families and clinical care. This will inform ongoing solutions through operational improvement and professionalization of the OPO workforce to a high level of clinical competency and evidence-based procurement practice, as well as iterative policymaking.

We note that such process data transparency is already standard in mature international procurement systems (for example, see England and Australia), as well as easily possible within the current U.S. procurement system. In fact, 7 OPOs have already committed to voluntarily sharing such process data via the Federation of American Scientists, writing to Congressional leaders that "this is data which can be easily and readily shared by all OPOs."

Such process data would also present an opportunity for CMS to strengthen its QAPI process, given that such data is necessary to develop a robust understanding of best practices, and, by extension, would give CMS the ability to set clear, quantifiable improvement goals and a sound evidence basis for clinical practice standards for OPOs, and to objectively track whether or not each OPO was actually making progress on these functions.

We are aware that some OPOs - presumably afraid of the accountability that such patient-centric transparency would enable - are already distributing talking points for potential inclusion in RFI responses that such transparency would constitute a reporting burden. This is nonsensical, given - per above - that this is data that all OPOs already collect, as well as made in bad faith, given that OPOs lobbied aggressively in the previous rulemaking process for a massive reporting burden for hospitals to enable a metric based on ventilated deaths.

Lastly, with such data transparently available, CMS can also update its current definition of "Urgent Need" in two critical ways to allow for decertifications of OPOs who are failing their constituents either by (1) providing highly variable rates of timely responses to donation referrals across patient groups known to experience health disparities, or (2) severely failing against the donation and transplantation rate metrics.

Currently, "Urgent Need" is defined as "occur[ing] when an OPO's non-compliance with one or more conditions for coverage has caused, or is likely to cause, serious injury, harm, impairment, or death to a potential or actual donor or an organ recipient."

It is worth noting that no OPO has ever lost its contract for any reason, including for "Urgent Need", despite acute patient safety issues as well as massive underperformance in organ recovery, both of which result in unnecessary patient deaths.

The current definition of "Urgent Need" is overly narrow for 3 reasons:

1) It is unclear what "serious injury, harm, impairment or death" an OPO can cause to an "actual donor", who, by definition, would already be deceased;

2) While applying this standard to an "organ recipient" is reasonable, the current definition ignores that most of the harms caused to patients result from severe mismanagement, rather than acute patient safety issues. For example, while much media attention has been paid to the South Carolina OPO sending the wrong lungs to a patient in 2018, resulting in their death, according to CMS's data in the Final Rule, 120 people died unnecessarily because of that same OPO's failure to operate in the top 25% percentile. While we appreciate that the general remedy for these failures is decertification at the conclusion of a certification cycle, CMS should consider broadening the definition of Urgent Need to include severe performance failure; and

3) As alluded to above, the current definition in no way includes an assessment of how equitably an OPO does or does not serve its community. To the extent CMS publishes

OPO process data, it can update Urgent Need to include whether the OPO has a variability in its timely response rates to donor referrals across racial and ethnic groups. For example, according to the most recent 2019 CMS data, the New Jersey Sharing Network is a Tier 1 (high performing) OPO, and yet the same data show that it is one of the lowest performing OPOs based on procurement rates for Black donors. In alignment with the Executive Order on Advancing Racial Equity, CMS should not consider an OPO high-performing if it systematically fails minority populations, and certainly should not scale this racially inequitable performance into other geographies.

Considering the above points, a potential definition for Urgent Need could be: *"occur[ing] when an OPO's non-compliance with one or more conditions for coverage has caused, or is likely to cause, serious injury, harm, impairment, or death to a potential or actual donor or a potential or actual organ recipient, or inferior service to any patient group(s) which experience health disparities, as defined by variable rates of service at any point in the OPO's process data."*

Related, CMS has an opportunity to update Conditions for Coverage to make OPOs more transparent, effective, and accountable (as noted elsewhere in this RFI response, because OPO failures disproportionately harm patients of color, so too will improving, standardizing and professionalizing OPO practices disproportionately help patients of color).

A comprehensive report from alumni of the U.S. Digital Service - endorsed by all 5 past, bipartisan HHS Chief Technology Officers - analyzed the OPO operational process (see process map) and proposed the following reforms to OPO conditions for coverage in order:

§ 486.322 Condition: Relationships with hospitals, critical access hospitals, and tissue banks. CMS can clarify:

- Hospital agreement should include protocols for both donation after brain death (DBD) and donation after cardiac death (DCD) cases.
- Increase designated requestor training for hospital staff to at least quarterly

§ 486.324 Condition: Administration and governing body. CMS can clarify:

- All OPOs should recover organs from donors after cardiac death and have policies in place for their protocol on how to do so.

§ 486.326 Condition: Human resources. CMS can clarify:

- OPO should have staffing measures in place for when interacting with potential donors' next of kin for donation authorization. To the extent possible, preference should be for staff to reflect the demographics (in terms of race and language) of the community in the OPO's DSA. Additionally, staff should undergo cultural sensitivity training for the demographics represented in their regions.
- Specifically for standards on qualifications, individuals involved in donor assessment, procurement, and placement should have clinical experience or documented clinical training.

- For standards on staffing, rule out of medical suitability for organ donation must be done by individuals with a clinical background; and OPOs must have a sufficient number of qualified staff to respond to 100% of potential donor referrals within an hour, including by going onsite in all cases to the extent possible.
- For standards on education, training, and performance evaluation, individuals involved in donor assessment, procurement, and placement must undergo annual continued education clinical training. Individuals directly involved in, or who supervise, clinical donor management must undergo or have documented training on deceased donor management protocols and best practices. Individuals involved in speaking with next of kin for donation authorization should undergo training on donor family communication best practices, implicit bias, health equity, and trauma-informed care.

Note: as additional context to the above, and building on an earlier allusion to the fatal patient safety error at the South Carolina OPO, it is our understanding that that OPO's Chief Medical Officer, at the time of that error, was not licensed to practice medicine in South Carolina. We raise this point to call attention to a deeply concerning gap in the legal system wherein there is no clinical expertise or training required to serve in seemingly-clinical function at an OPO because, legally, deceased people are no longer considered people.

This lack of clinical training can result in patient safety lapses (e.g., by having people without clinical training reading misreading blood tests, especially after the patient has received blood transfusions, can cause serious or fatal harm to the downstream transplant recipients); and can also depress organ transplantation rates more universally, as mismanagement of the donors can result in lower organ yields for donors, even in the event that some organs are still recovered. CMS can and should correct for this through the requirement of clinical experience for OPO professionals.

§ 486.328 Condition: Reporting of data. CMS can clarify additions related to:

- Timeliness of OPO staff follow-up on eligible donors, and whether follow-up was onsite;
- Data on demographics of donor families/next of kin who were approached for authorization (including at a minimum race/ethnicity, age, whether they were HIV-positive, and whether they were an extended criteria/marginal donor); and
- Data on staff demographics (gender, race, languages spoken) and background (clinical/non-clinical).

§ 486.330 Condition: Information management. CMS can clarify:

- Addition to referral information requiring the OPO to create a record for every referral using CMS provided data protocol: The record must include, at a minimum: date, time, and origin of referral; who at the OPO received the referral; how it was triaged; how long it took OPO staff to follow-up and whether it was onsite or not. CMS and OPOs should be analyzing this data as part of their QAPIs.

§ 486.342 Condition: Requesting consent. CMS can clarify that the OPO should also ask about and clearly document any family time constraints, as well as provide the following information to the donor family:

- Costs associated with donation (there should be none)
- Timeframes for the donation decision and donation process, including any potential delays to funeral arrangements
- The donor's eligibility to donate and ability for the family to decide which organs to donate
- The need for organs and the potential to help others, especially within that donor's demographic community if applicable
- The treatment of the donor's body during organ recovery
- If applicable, an explanation of a brain death diagnosis

§ 486.344 Condition: Evaluation and management of potential donors and organ placement and recovery. CMS can clarify:

- Within potential donor protocol management, the OPO must implement a system that ensures that a qualified physician or other qualified individual with a clinical background is available to assist in the medical management of a potential donor when the surgeon on call is unavailable.
- Within testing, utilize virtual crossmatching as the primary method for donor and recipient matching to the extent possible. Ensure that the potential donor's blood is typed using two separate blood samples and have a protocol in place for donors who have undergone transfusion.
- Within the collaboration with transplant program standards, the OPO should also have a protocol in place for donors who have undergone blood transfusion.
- For donation after cardiac death, all OPOs should recover organs from donors after cardiac death and allow for the mention/socialization of donation after cardiac death prior to the family making the decision to stop/withdraw care.
- Additionally, given that some hospitals express reticence to participate in DCD cases (either performing or receiving) as they increase their mortality rate thereby impacting their national benchmarking scores (a situation amplified if the DCD withdrawal occurs intraoperatively), CMS should ensure practices are in place so that such reporting does not count against hospitals performing DCDs, particularly as regards counting of deaths in the operating room.

§ 486.346 Condition: Organ preparation and transport. CMS can clarify:

- The OPO must document how the organ is transported, track its condition during transport, and its final cold-ischemic time at arrival to the transplant center.

§ 486.348 Condition: Quality assessment and performance improvement (QAPI). CMS can clarify:

- These actions should include participation in peer-reviewed academic research to the extent possible.

Some OPOs will likely object to transparency measures that will lead to increased accountability. In the past, such objections have often been couched in the positive framing that all reforms should have "consensus" from the entire organ donation and transplantation system, which is a flowery way of, in practice, advocating that OPOs should have full veto power over any efforts to hold them accountable by withholding support for any reforms.

CMS has rejected this specious argument in the past and should do so again. Related, and In this context, however, we highlight internal emails from OPO and UNOS decisionmakers recently unsealed by a Federal judge in which they hold the exact opposite position on the argument for consensus. Specifically, OPO CEO Alex Glazier wrote to then-UNOS President Yolanda Becker that: "*Sometimes as leaders we are too focused on consensus building. Both sides do not always have equal legitimacy and playing neutral arbitrator is not what leadership is about."*

In that, we agree: all points do not have equal legitimacy, and CMS is right to always decide on the side of patients and transparency. In that vein, we highlight recent fact-checks to flagrantly uninformed AOPO position papers, as well as a recent Congressional hearing in which the current AOPO CEO, in response to questions regarding AOPO's repeated misrepresentations and disinformation, testified that he does not have a "deep understandings" of the OPO regulatory system.

5. OPO Assessment and Recertification and Competition

Questions addressed:

1. Are there additional factors or criteria that CMS should consider when determining which OPO should be selected for an open service area?
2. Should CMS consider other performance measures when selecting an OPO for an open DSA? Such measures could include performance on converting donor referrals to potential donors or the number of "zero organ donors" or the number of organ discards (see section C.5. for additional information), reflected in the discard rate, or improvement, over time.
3. Should CMS continue to consider the contiguity of an OPO to an open DSA?
4. What are the challenges that an OPO would face if taking over an open DSA? Are there specific disincentives within the current regulatory requirements to taking over an open DSA?
5. Are the current CMS requirements for a governing body and advisory board adequate for OPO governance? Have OPOs included additional board positions or structures beyond what is required by CMS to improve operations? What structure best serves accountability, and efficient and effective organ procurement?
6. What would be the anticipated impact from consolidation or expansion of the OPO community? Would consolidation or expansion of OPOs facilitate increased competition and improved performance or have a negative impact?
7. Any other helpful information that could inform potential changes to the current recertification and competition processes.

To help inform the best ways for CMS to support successful OPO decertifications/expansions, we partnered with the Bridgespan Group to perform an analysis of historical OPO mergers. (Note: while AOPO lobbying points have tried to paint OPO mergers as unprecedented, there have actually been 71 mergers in the history of the OPO industry, and never once has this caused adverse outcomes, as clearly articulated by past AOPO President Diane Brockmeier and her colleague, OPO CEO Ginny McBride.)

We also note that existing OPO Conditions for Coverage § 486.330 (d) explicitly states: "*(d) Format of records. The OPO must maintain data in a format that can readily be transferred to a successor OPO and in the event of a transfer must provide to CMS copies of all records, data, and software necessary to ensure uninterrupted service by a successor OPO. Records and data subject to this requirement include donor and transplant beneficiary records and procedural manuals and other materials used in conducting OPO operations.*"

To the extent that an OPO suggests that future mergers may be more disruptive than the 71 historically successful mergers because it is "non-voluntary" - which was a regular lobbying point of AOPO and many OPOs through the last rulemaking process - that OPO would seem to be implying that they plan to actively and purposefully violate CMS conditions for coverage, and to do so with the intent of harming patients, and even an expression of such a sentiment should call into question that OPO's fitness for public service.

In this report, we and Bridgespan explored various factors to assess "to what extent these differences should be accounted for when selecting an OPO to take over an open territory", including OPO size, governance model, and geography, as well as geographic proximity to/contiguity with any DSA an OPO is seeking to acquire (see Appendix E of Bridgespan Report).

Ultimately, the analysis concluded that: *"After exploring these factors with OPO leaders and field experts, we believe OPOs with good leadership, as well as a strong track record of performance and the systems and capacity to quickly and seamlessly establish local operations in the new DSA, can overcome any challenges that these differences may pose. The key point for patients is that any change would entail a higher-performing OPO assuming leadership of an underperforming OPO's service area."*

There are, however, additional steps CMS can take to ensure that OPOs interested in acquiring additional territories are best positioned to develop as informed proposals as possible for CMS's consideration, as well as to ensure that acquiring OPOs are able to ramp up operations as quickly and seamlessly as possible.

Specifically, Bridgespan analysis suggests:

"OPO data that CMS could explore making available to OPOs prior to competing for a service area in order to inform decision making about whether to apply:

- Procurement operations
    - All referral data and disposition data broken down by hospital and by month (in order to project productivity and develop a staffing structure, strategic plan, and financials)
- Finances
    - Key financial statements related to the OPO and any supporting organization they have established
    - Detail on prior years' organ acquisition charges/standard acquisition charges (by organ)
    - All liabilities, including how they've funded any building or other capitalized projects (as relevant)
- Hospital relationships
    - Agreements with donor hospitals and transplant centers
    - Key contacts of all major hospitals
    - An overview of which hospitals the OPO engages with on tissue procurement
- Staff and governance
    - Organizational chart
    - Board makeup

<u>OPO data / information that CMS could explore making available to an OPO after being selected to take over a service area</u>

- Procurement operations
    - Standard operating procedures for critical procurement functions, including death record review processes
- Finances
    - Investment policy/strategy
- Hospital relationships
    - Plan for how donor hospital and transplant center contracts will be transferred to the new OPO Staff and governance
    - Pay ranges and bonus structure associated with each type of position
    - Personnel files
- Transition plan
    - Plan for whether entity will seek to enter into a consolidation with the higher-performing successor OPO and transfer assets
- General
    - Strategic plan (as relevant)"

Additionally, and as further expounded upon in this RFI response, CMS should also consider an OPOs technological and logistics management capabilities in assessing which OPO should be awarded a new DSA, given that such capabilities will only be of increasing importance as an OPO increases the size of its DSA and its workforce.

Lastly, we also note that an acquiring OPO need not merge its existing DSA with any additional DSA(s) it will acquire. This may remove a disincentive for that OPO, given that, even if it fails to sufficiently improve the territory(ies) it acquires, it need not also lose its original DSA (assuming it is able to maintain sufficient performance).

Should CMS consider additional metrics, such as those that measure equity in organ donation or an OPO's success in reducing disparities in donation and transplantation, and how should this be measured?

CMS should absolutely consider an OPO's success in reducing disparities in procurement and transplantation. Specifically, when considering bids from multiple OPOs to take over the same DSA, CMS should significantly weigh each OPO's donation rate for racial and ethnic minority patient groups, as well as their rate of timely response to donation referrals among any patient group known to experience health disparities.

OPOs must demonstrate, with objective evidence of their own clinical procurement practice, that all efforts are made to ensure equitable care is provided to any potential donor and donor family. With currently available data, we cannot yet show that even high performing OPOs under the latest CMS metric provide equitable clinical care across all marginalized patient groups (such as ethnic minorities, HIV+ patients, older age patients, LGBTQ+ patients, and rural patients).

In addition to ensuring that territories up for bid are awarded to the OPOs with the best demonstrated track record of equitable service, this would also have the practical effect of further incentivizing higher-performing OPOs to provide more equitable service in their own DSA such that they can position themselves as stronger candidates to absorb additional DSAs as well.

What would be the anticipated impact from consolidation or expansion of the OPO community? Would consolidation or expansion of OPOs facilitate increased competition and improved performance or have a negative impact?

Along with the Bridgespan Group, with participation from many OPO CEOs, as well as the public endorsement of the two immediate past AOPO presidents, we performed rigorous analysis, including analysis of historical OPO mergers, to create a roadmap for how CMS can implement OPO decertifications seamlessly, and while foregrounding equity considerations in the process. Counter to AOPO lobbying points, the data is clear that there is no reason to believe that such mergers would in any way be disruptive.

In fact, as noted a recent past president of AOPO, *"Some of our colleagues have tried to paint any changes as destabilizing and unprecedented, positing that it will lead to situations in which areas of the country do not have OPOs at all. But this is simply not grounded in HHS's proposal... There were originally 128 OPOs, and after decades of consolidations there are now [57] OPOs; never has this process been disruptive. Forcing OPOs to continually earn their*

contracts is a patient-centric accountability mechanism, ensuring that OPOs operate with the urgency befitting the life-and-death consequences of this work."

Decertifications of Tier 2 and 3 OPOs - and the related expansion of higher performing OPOs into the DSAs of the failing OPOs - brings numerous benefits to patients broadly, and disproportionately to patients of color.

First, it is important to consider the effect that the simple credible threat of decertifications will have on the OPO system broadly. Historically, OPOs have faced no functional pressure to perform well: OPOs have geographic monopolies; have had legally unenforceable regulations; are the only major program in healthcare that still operates on the anachronistic cost-reimbursement model; and have been functionally allowed to self-regulate via UNOS, which investigative reporting has found to serve a protectionist rather than an oversight function. In this absence of regulatory, financial, or oversight pressures to improve, the OPO industry has spent at least a decade backsliding.

However, there is already evidence to suggest that the very introduction of the credible threat of decertifications will improve OPO performance. Peer reviewed research finds donation rates relative to actual potential grew by 12.3% from 2018 to 2019 (a year of extremely heightened OPO scrutiny, including the Executive Order and NPRM) - a change nearly five times the median growth over the preceding decade.

These gains were also most pronounced in donor categories in which OPOs have historically most underperformed, including older donors, non-drug overdose deaths, and donors after cardiac death (DCD), suggesting these gains were a function of increased OPO effort.

In one of the most pronounced examples, peer-reviewed research finds, over this year, the Indiana OPO approached 57% more families for donation than in the previous year and recovered 44% more donors. Additionally, as one HHS senior official noted, OPO failure is a close proxy for its substandard treatment of minority patient populations; by holding OPOs accountable to their performance, the likely impact will be creating incentive structures for OPOs to allocate resources serving underserved communities, rather than, as has been the case historically, on expenditures unrelated to patient care.

As noted in the Bridgespan report on OPO mergers, further strengthening the case for decertifications: there is no evidence to suggest that HHS's alternatives have ever been successful. Specifically, in 2012, HHS placed an underperforming OPO on a "performance improvement plan" in lieu of decertification, in hopes that such a governmental plan would lead the OPO to turn around. As noted in the Washington Post, since 2012, CMS has required the OPO to submit at least three "corrective action plans." Despite such plans, for at least the past eight years, the OPO "has consistently registered one of the poorest performances in the nation," and "ranked as the country's second-worst OPO [in 2017]."

Additionally, mergers themselves - in addition to allowing higher performing OPOs to serve even more patients - are actually likely to improve the acquiring OPO(s). Specifically, research finds that more than 60% of the cost of an organ is OPO overhead, and our analysis with the Bridgespan Group conservative estimates that the consolidation of two average-sized OPOs would create economic synergies exceeding $4 million annually - which can and should be re-deployed to hiring and supporting more frontline staff and to serving hospitals in minority communities (which actually helps patients), areas in which the OPO industry has dramatically underinvested.

Specifically, this analysis finds: “These significant resources could be reallocated to hire more than 50 organ recovery coordinators (focused on procurement and logistics), or more than 59 family services coordinators (focused on support and guidance of donor families); increase pay of existing coordinators; or some combination of these options based on the needs of the OPO. While individual finances and staffing circumstances vary, this illustrative analysis shows significant opportunities to redeploy resources when a high-performing OPO takes over a low-performing OPO’s service area, with funds then free to be reallocated to the costs of expansion or to the frontline staff who drive procurement and transplantation outcomes.

“In addition, there might be one-time savings that could support costs associated with a merger or expansion, most notably in real estate. The average OPO has over $9.3 million in fixed assets (land, buildings, and equipment), including real estate. Following consolidation, the OPO operating in the new territory would require some local office space to continue operations, but would not require two extensive headquarters buildings or multiple call centers.

“It is important to understand that much of OPO failure comes from OPO understaffing of front-line workers, as well as underpaying and under-supporting front line staff, leading to unacceptably low response rates to donor referrals (particularly for donors of color, given that many OPOs deprioritize communities of color in their triage process), as well as incredibly high rates of attrition, with research finding that OPO staff yearly attrition rates to range from 17% to 28% and an average job tenure of less than three years.

“In sum, decertifying Tier 2 and 3 OPOs will create useful pressure on all OPOs to improve; has been shown unequivocally in historical data to be seamless and non-disruptive; and would actually have the net effect of creating cost efficiencies as well as regulatory incentives for OPOs to address what is likely the single biggest driver of performance failures - the gross under-resourcing of frontline staff, leading to unrealistic expectations for coordinators and an unsustainable work environment.”

6. Organ Recovery Facilities

Question addressed:

Can the OPO CfCs address the issue of organs that are lost during transport to a transplant program?

While we appreciate the spirit of the question, it is important to note that the term “Organ Recovery Center” does not have a standard definition across OPOs. For example, some OPOs own and operate a dedicated “Organ Recovery Center”, while others rent an “Organ Recovery Unit” within a larger hospital. There also is currently very limited transparency around not only which OPOs even have some version of an ORC, but also into the ways in which OPOs currently use them, and, by extension, their efficacy.

While there may be some potential for Organ Recovery Centers to improve donation and transplantation rates in certain cases, and under the right reimbursement models, there is currently very limited data to support their efficacy at meaningful scale, and little is understood into the ways in which they might be abused, given are certainly more lucrative for OPOs, and that some OPOs have a clearly documented history of prioritizing financial gain above patients’ best interests. As mentioned above, there is not yet even complete, publicly available data regarding which OPOs even own or use ORCs or when such practice began; scaling this before further review and documentation of best practices would be premature, risky, and not supported by an empirical evidence base.

The data that does exist about ORCs is not peer-reviewed, and the cases that those OPOs bring to their ORCs are not representative samples of their donation population (i.e., OPOs often talk about having “better outcomes” at cases in their ORC, though it is likely that this may largely be a function of selection bias - i.e., patients selected to move to the ORC have already successfully moved through the OPO’s current clinical process).

Additionally, the OPOs that have publicly disclosed that they use ORCs are evenly distributed across Tiers 1, 2 and 3, which suggests that there is not necessarily even a correlation between using an ORC and high OPO performance.

This may be a function of limited ORC efficacy, and/or a major contributing factor is likely the wide variability in how OPOs use them, given the troublingly non-standard practices at OPOs in the absence of process data and clear clinical standards. Before scaling ORCs, CMS should first more rigorously study their efficacy, including to understand how they can be used to advance patient outcomes while also guarding against OPO profiteering and metrics-gaming.

One point, however, in the absence of firm data: there is also certainly no need for all OPOs to have an ORC, especially given that some number of OPOs may soon be decertified. The most prudent step forward would be for CMS to work with one or two high-performing OPOs that have ORCs on a demonstration project in order to gather the data necessary to ascertain whether, how, and in which circumstances ORC use can responsibly improve outcomes (Mid-America Transplant and Southwest Transplant Alliance would be a logical choices, given their demonstrated commitment to transparency).

In the event that ORC efficacy is proven, the most prudent model may be for CMS to establish 3rd party owned ORCs so that the entire ORC isn’t lost if an OPO is decertified. (Anecdotally,

there is a sentiment in the OPO industry that if an OPO is able to quickly establish an ORC that this will serve as a prophylactic against CMS decertifying it for performance failure.)

7. Board Governance & Improved OPO Oversight

Questions addressed:

Are the current CMS requirements for a governing body and advisory board adequate for OPO governance? Have OPOs included additional board positions or structures beyond what is required by CMS to improve operations? What structure best serves accountability, and efficient and effective organ procurement?

We are seeking ways to harmonize policies across the primary HHS agencies (CMS, the Health Resources and Services Administration (HRSA), and the Food and Drug Administration (FDA)) that are involved in regulating stakeholders in the transplant ecosystem so that our requirements are not duplicative, conflicting, or overly burdensome. Are there any current requirements for transplant programs, ESRD facilities, or OPOs that are unnecessarily duplicative of or in conflict with OPTN policies or policies that are covered by other government agencies? What are the impacts of these duplicative requirements on organ utilization and transplant program/ ESRD facility/OPO quality and efficiency?

Alumni of the U.S. Digital Service produced a comprehensive report "to closely examine the current governance and oversight structure of the organ donation system to identify gaps, conflicts, and impotencies", and identified problematic oversight gaps in 6 key areas:

- OPO failure to recover enough organs: OPOs can easily hide or manipulate their outcome measures in the current system, leading to thousands of organs going unrecovered and/or untransplated, and patients needlessly dying on the waitlist. This compromises not only oversight and regulation, but also academic research, which would ideally function as a means to inform ongoing policy considerations.
- Complaints process: OPOs are expected to self-report patient safety issues to the federal contractor tasked with optimizing their performance, the United Network for Organ Sharing (UNOS). But, even in UNOS' determination, the voluntary nature makes these reports "subject to underreporting." We found that few complaints are ever lodged against OPOs due to a lack of confidence that change will occur, fear of retribution if someone makes their concerns known, and unawareness of the reporting process.
- Conflicts of interest: Committees and boards within UNOS, as well as reviewers at academic journals, are often filled with OPO leaders, board members, and/or other member representatives. This leads to situations such as leaders from underperforming OPOs deciding their own performance review process or suppressing unfavorable research.
- Communication across a diffuse government structure: The groups within the Department of Health and Human Services (HHS) that ultimately oversee the organ donation system are reported to have a lack of communication and collaboration.

- Financial incentives: The large gap in oversight of financial incentives and resource allocation has led to issues such as OPOs spending a disproportionate amount of resources on lucrative tissue procurement, and OPOs spending taxpayer money on things like football tickets and lobbying expenses, while under-resourcing key programming more likely to lead to life-saving organ recoveries, such as hiring and supporting frontline staff.
- Technology and security: UNOS technology is outdated, inadequate, and insecure, yet government oversight arms are not auditing it, managing it in any meaningful capacity, or otherwise holding it to an appropriate standard.

Related, OPO boards have largely abdicated their oversight responsibilities. This occurs for various reasons. In some cases, this results, at least in part from financial conflicts of interest. CMS should disallow the OPO practice of compensating their board members, including via contract work or excessive board perks.

As the report found, this has contributed to a culture of cronyism on OPO boards: "However, many stakeholders we talked to suggested that many OPO boards are plagued by ineffectiveness, conflicts of interest, and inconsistent governance.' [OPO leadership] are not accountable to anybody but the people they choose to be on their boards," explained one former government official, "so it serves them to have people on their board who are their buddies.'"

This problem is further exacerbated by a lack of transparent and objective process data, enabling a dynamic in which OPO boards do not have sufficient information to hold OPO management accountable. As a previous report we produced with the Bridgespan Group found, one OPO executive noted: "*The OPO strategy is to confuse people with data – always have data available to tell your board or CMS that you're doing good: yield … increase in hearts, DCD rates… 'As long as I've got something, I'm good.'*"

CMS can make major strides in activating meaningful OPO board oversight via mandating full transparency with OPO process data and strictly disallowing compensation - in any form - to OPO board members for their board service. Additionally, to ensure there is no information arbitrage, CMS should send regular data reports to OPO boards, rather than just to OPO management, highlighting any outcome or process point data in which the OPO is performing below the median.

In parallel, as expounded upon elsewhere in this RFI response, reimbursement reform for OPOs will also enormously help strengthen OPO oversight. As highlighted in investigative reporting - and now animating the House Oversight Committee investigation - OPOs have abused the cost-reimbursement structure to fight against oversight and accountability.

For example, OPOs have enormously increased influence spending to hire lobbyists and PR firms to push disinformation and to fight against accountability, including via astroturf campaigns purporting to be patient groups; have co-opted other stakeholders to submit public comments on

their behalf without disclosing a paid "advisory" relationship with their OPO; and have exploited loopholes in the disallow of reimbursement for lobbying expenses by classifying such costs as "board expenses" (e.g., leveraging paid board members for political access) or funneling such expenses through AOPO, which has now shifted its legal structure to 501(c)6 to function as the OPO industry's lobbying arm.

Consider, for example, OneLegacy, which paid many of its board members in 2019, including $100,000 to one board member and $50,000 to two others $50,000. OneLegacy is consistently among the worst performing OPOs in the country, is under investigation from the House Oversight Committee, has been found by the Office of the Inspector General to misspend hundreds of thousands of taxpayer dollars on retreats to 5-star hotels, and has been profiled in the LA Times and the Project of Government Oversight for unethical behaviors, including anti-patient lobbying and failing to disclose severe conflicts of interest in its tissue recovery business. Despite this, however, the CEO has kept his job for decades and is among the highest paid OPO CEOs in the country; it is clearly reasonable for patients to wonder whether the taxpayer-funded payments to OneLegacy board members have compromised their willingness to hold the CEO accountable in patients' interests.

Similarly, investigative reporting has found that "a prominent CEO told colleagues the industry should engage in 'protracted litigation' to 'tie up the government for years' if it tries to decertify any of the organ procurement organizations that fail to meet performance standards required by the proposed reform." Meaningful reforms to OPO reimbursement, however, will take away the functional blank check OPOs are given to fight against oversight and accountability.

Along similar lines, given that OPOs are the only major program in healthcare to operate on a cost-reimbursement basis, which they have consistently abused to protect their own interests rather than advance patient and societal interests. Consider that, in the estimation of one senior government official: *"Sometimes the best way to file a complaint [about the organ donation system] is to go to the news media."*

This is further supported by recent statements from Chairman Raja Krishmamoorthi, including that *"what spurred the latest oversight efforts [from the House Oversight Sub-Committee, which he leads] were just reports in the press honestly about lavish spending, extravagant practices, and high compensation at these organ procurement organizations and just people languishing on the waitlist and dying for lack of an organ."*

Research shows that scrutiny of OPOs in press and otherwise likely improves OPO performance, and both HHS officials and legislators acknowledge that media attention on OPO failures catalyzes meaningful reforms, and yet OPOs have functionally unlimited, taxpayer resources to silence employees and patients with legitimate complains via taxpayer-funded non-disclosure agreements and out of court settlements.

For example, there are several documented cases of OPOs settling lawsuits out of court, for various complaints ranging from wrongful death, to racial, sex, and job discrimination, and

OPOs are able to use taxpayer dollars to settle these lawsuits out of court. This presumably undercuts pressure to not engage in such behaviors, as well as ensures that the government and general public do not learn about problematic practices. CMS should disallow OPOs from including such litigation and settlements into their taxpayer-funded reimbursements.

Related, CMS should strongly consider re-absorbing as much oversight as possible given the severe conflicts of interest in the OPTN. UNOS - which is currently the a bipartisan Senate Finance Committee investigation into its conflicts of interest and industry protectionism - has never once taken meaningful action against any OPO, despite documented evidence of Medicare fraud, conflicts of interest, and criminality, as well as what the Senate Finance Committee has characterized as "OPOs severely underperforming for decades."

This protectionism has been allowed in large part because, in addition to facing no competitive pressures to retain its contract, there are also no governance checks on UNOS. This has enabled a dynamic wherein investigative reporting from the LA Times characterized as a *"reluctant enforcer"... with "collegiality is built into [its] very structure"*, further noting that *"the little-known organization that oversees the nation's organ transplant system often fails to detect or decisively fix problems at derelict hospitals -- even when patients are dying at excessive rates… When it does act, the UNOS routinely keeps findings of its investigations secret, leaving patients and their families unaware of the potential risks, interviews and confidential records show.*"

Similarly, Forbes has characterized UNOS as a *"cartel"* and *"the federal monopoly that's chilling the supply of transplantable organs and letting Americans who need them die needlessly",* as has the New York Times editorial board called on HHS to *"revisit the UNOS monopoly"* given the *"astounding lack of accountability and oversight in the nation's creaking, monopolistic organ transplant system [that] is allowing hundreds of thousands of potential organ donations to fall through the cracks."*

This marries with internal emails from UNOS CEO Brian Shepard, unsealed by a Federal judge after UNOS spent countless taxpayer dollars to keep them private, in which Shepard wrote that [UNOS doesn't] have a real board." As Senators Chuck Grassley and Todd Young wrote to the Office of the Inspector General regarding UNOS's complete, utter and reprehensible abdication of oversight, leaving thousands of patients to die unnecessarily every year, *"We can no longer stand by idly while the fox guards the hen house."*

As the U.S. Digital Service alumni report found, there is a major gap in OPO oversight as well as a shifting narrative regarding who bears responsibility for such oversight:

"Tellingly, even UNOS appears to have previously acknowledged its role in providing oversight. As of February 2020, in the FAQ section of UNOS' own website UNOS stated that it 'manages the first two [of three] steps' of 'OPO oversight.' Only after the Senate Finance Committee opened an investigation into UNOS' abdication of such oversight did UNOS change the language on its website to distance itself from oversight responsibilities, stating: 'Many people

think UNOS oversees every facet of the transplant process. We don't…UNOS is a forum for organ donation and transplant professionals to come together and determine how the national system should work.' According to one MPSC member, '[if UNOS actually wanted to], they could put their hands on OPO failures much more seriously than they have in the past.'

"In any case, one of two things must be true: either the OPTN is responsible for such oversight and has been delinquent in exercising its authorities, in which case HHS should consider UNOS' track record in future contracting cycles; or HHS can determine that the OPTN is not responsible for such oversight, and, by logical extension, should then reabsorb such functions into an Office of Organ Policy to ensure that OPOs are meaningfully regulated on behalf of patients and taxpayers. We note however, that in the first instance, regulatory capture could remain a persistent concern."

While as frustrating as UNOS's shapeshifting may be, its new acknowledgement that it does not consider itself responsible for oversight makes abundantly clear that HHS must re-absorb such functions itself, and the previously mentioned report offers actionable suggestions for how such an Office of Organ policy could be structured and staffed.

(Note: While this may seem like a significant expansion of talent and resources, each additional kidney transplanted constitutes a cost-savings to Medicare of $1.45M in avoided dialysis costs, meaning such investment in meaningful oversight more than pays for itself.)

"If the Office of Organ Policy were based in the Office of the Secretary or in Office of the Assistant Secretary for Health (OASH), the authority to enact change can come from the OPTN Final Rule, which gives the HHS Secretary (and its designees) broad leeway to gather the information necessary to carry out their responsibilities. Additionally, HHS lawyers could interpret NOTA to focus on its goals and objectives, rather than the OPTN structure.

"The OOP needs to be staffed with not only the right skills and knowledge for the wide variety of functions needed to oversee the organ donation field, but those experts also need to be free of any vested interests with UNOS or OPOs in order to avoid further entrenchment of conflicts of interest. As one OPO CEO described, "[HHS] would have more confidence if they had experts around them who didn't have a vested interest in winning the contract. They need to be able to scan the horizon, identify opportunities to improve governance, and deploy the improvements in a systematic way. [See process maps of current and suggested future organ donation governance structure.]

"Skill sets the OOP should prioritize in engaging talent include:

- *Technologists to interface with the OPTN organ matching technology (currently DonorNet) and continually monitor it for efficacy and improvement as well as system and technology accountability (note: this could come in the form of details from the excellent United States Digital Service, which already has strong operations within HHS);*
- *Clinical experts in organ transplantation to oversee clinical standards, policy, and allocation algorithms;*

- *Financial experts, including with expertise in forensic accounting, to evaluate OPO and OPTN resource allocation, and flag inappropriate reimbursement claims as needed;*
- *Health care financing experts to work with the Centers for Medicare to evaluate alternative OPO financing models with the goal of aligning OPO financial incentives with the goals of patients and taxpayers (i.e., maximizing life-saving organ recovery and transplantation);*
- *Leaders who can help address racial inequities in the organ transplant system*
- *Merger and Acquisition expertise for OPO consolidations, since that is the most likely way to decertify an OPO moving forward;*
- *Systems thinkers who will focus, urgently and holistically, on addressing systemic rather than acute problems;*
- *Analysts with the ability to evaluate policies and regulations – HRSA has over-relied on external contractors like the SRTR, especially given potential SRTR conflicts;*
- *Market design economists to optimize living kidney donor chain systems;*
- *Open data experts who can coordinate with external researchers.*

"The OOP may be able to do things that HRSA previously could not via authority as a designee of the HHS Secretary. We suggest leveraging this opportunity by prioritizing hiring experts with the skill sets outlined above to tackle these longstanding problems. For example, if the OOP can get access to audit UNOS' tech stack code (which HRSA previously could not), it makes sense for OOP to hire digital services experts; similarly, if the OOP can access UNOS Membership and Professional Standards Committee (MPSC) files, it makes sense to engage oversight experts.

"The OOP should provide a cohesive strategic vision and ensure alignment of practices and policies across all of HHS consistent with unified goals. In terms of the staffing structure, the biggest difference between the OOP and the current diffuse governance structure will be that there is a director of the OOP who oversees all aspects of organ donation and transplantation. The ultimate responsibility would lie with this role to ensure that nothing is being missed and that the system is continually improving. In the current system, that responsibility does not lie with any single role. As a result, different entities only carry out the minimum of what they are tasked with, rather than taking a holistic view and proactive stance to address systemic issues.

"Under the OOP, there should be different staff overseeing transplant centers, OPOs, and the OPTN. Transplant centers and OPOs should have different staff because each requires different types of knowledge. Staff overseeing the OPTN and OPOs should be different to maintain separation of undue influence of the OPTN contractor on government OPO policies. Above all, the OOP should have a strong conflict of interest clause that says anyone in a leadership position at the OOP cannot then go on to work at or lobby for an OPO or the OPTN contractor afterward.

"Once the correct staff and structure are in place, there are several key steps that the OOP can take in their first few months to improve oversight and efficiency in the organ transplant system. Many of these actions will require the OOP to coordinate with various agencies involved with the

OPTN ecosystem. The OOP should become the conductor and coordinator of all agencies as it relates to OPTN and OPO issues. From the onset, the OOP should strive for transparency in their work and plan to give frequent updates and reports to Congress on the actions listed below.

- *Tech Audit: Utilizing tech experts, OOP should work with the United States Digital Service to do a thorough audit of the UNOS technology stack and pursue access to the code on which the technology is built. This code should be held up to modern technology standards and examined for security vulnerabilities. The OPTN contract should also be reviewed and the next RFP should be built to open up competition for potential new vendors.*
- *Complaint Audit: OOP staff should request and audit the complaint history handled by CMS and MPSC to evaluate what actions were taken or not taken for every complaint and re-open cases as needed. This should include investigating any conflict of interest for each MPSC member at the time when each complaint was processed. The goal is to take action on what may have been previously missed, as well as identify trends among the reports for systemic issues across OPOs.*
- *Revise Complaint Process: OOP staff should initiate a user-centered design project (potentially in conjunction with the United States Digital Service who have helped redesign other similar government systems) to both rebuild the complaint system and provide public education to all stakeholders (patients, transplant centers, hospital staff) on how to access and report complaints.*
- *Financial Audit: OOP staff should work with governmental partners to do regular audits of each OPO's finances to identify if there is ineffective resource allocation (such as understaffing of organ procurement, especially as compared to staffing for tissue procurement) or improper reimbursement claims. This should include reviewing executive compensation and how that compares to the OPO's performance, and advise on alternative reimbursement models (including for executive compensation) that would better harmonize resource allocation incentives with the goal of maximizing organ transplantation.*
- *Public Website: Given each OPO's regional monopoly status, the OOP should aim to bring more transparency to OPO performance and how that affects patients. One way to do this is to create an easily accessible public website showing OPO performance data and compliance according to the recently finalized outcome measure changes and its implications for patients.*
- *OPTN Policy: Review all current OPTN policies to evaluate if and how they contribute to racial inequities, including considering transparency requirements for how OPOs respond to potential donors. Review conflict of interest policies and how they've been implemented for both the OPTN and OPOs. For conflicts of interests that are unavoidable, there should be full public transparency made for every instance.*
- *Data Access Policy: Coordinate with SRTR and establish data access policies that would enable researchers safe access to OPO and OPTN data without the need for OPO or OPTN contractor approval. This is meant to encourage and enable independent*

academic analysis of OPO and OPTN performance, to bring fuller transparency and help continually improve the system.

- *Strategies to Optimize Organ Donation: OOP staff should further engage data experts to develop more effective and standardized strategies for optimizing organ donation. This should include identifying opportunities for better integration between donor hospital and OPO data systems to support faster identification of potential donors, and work with CMS to update OPO Conditions for Coverage relating to OPO processes. And it should include revisiting and updating CMS' definition of "Urgent Need" for use in decertifying failing OPOs. Along with OPTN oversight functions, the OOP should coordinate on several OPO governance functions currently held by CMS. At the top of this list is OPO certification, as specified in the Public Health Service Act. OOP would then set conditions for certification and CMS' conditions for coverage would point to the new certification conditions. Transferring this function to OOP would enable specialized auditors to focus solely on OPO site surveys and better understand the nuances of the organ donation system so that they can more readily identify problematic practices. Relatedly, the OOP should coordinate with the Center for Medicare on reforming OPO reimbursement policies to better incentivize OPOs to allocate resources properly and get more organs transplanted.*

"Another function is for the OOP to oversee quality measures and improvement programs pertaining to organ donation, including all complaints, learning collaboratives, and innovative projects. With the consolidation of these functions into one office, there can also be a consolidation of legal counsel. According to one government official we spoke to, "right now there are various legal counsels who each serve a different agency, and all only know that agency's part of the fractured system. Someone knows the 'CMS part.' Someone else knows the 'HRSA part.' What we need is someone who understands the 'organ donation part.'" A consolidated view including all of the legal components of regulations and laws pertaining to OPOs, transplant centers, and the OPTN, and understanding how any policies would impact each individually as well as broader systems dynamics across them would greatly benefit the policymaking process.

"Above all, it is important to clearly define the mission and directive of the OOP in order to empower and encourage its staff to do what it takes to constantly improve the organ transplant system to recover and transplant organs, rather than maintaining the status quo."

Lastly, we note that the creation of an Office of Organ Policy already has the expressed support of the House Appropriations Committee; Reps. Karen Bass, Katie Porter, and Raja Krishnamoorthi; Nobel Laureate Al Roth; and past NAACP President Ben Jealous.

Directly related to the goal of reabsorbing oversight (although, in any case, very much worth pursuing regardless), the U.S. Digital Service alumni report also highlights opportunities to strengthen the CMS complaints reporting process.

Specifically, *"Anonymous complaints should be able to be submitted in a simple, accessible, and clear way. HHS should do "root cause analysis" of incidents as part of their recertification process and site reviews. And the government should have access to all complaints or even shift its role to become the interface for all incoming complaints. As noted above, the OOP can have a heavy role in this change by initiating this rebuild and by seeding education campaigns for industry stakeholders about how to access and use the complaint system."*

Relatedly, in this process CMS can more actively encourage stakeholders to submit complaints (historically - and certainly with complaints to the OPTN - stakeholders have been reticent to make complaints for fear of industry retribution, especially given a lack of belief that such complaints will be acted upon).

For years, OPOs have self-insulated from criticism by pushing the narrative that any criticism of the donation system will undermine public trust and, by extension, decrease donation rates. Interestingly, peer-reviewed research has shown exactly the opposite to be true: that criticism and critical analysis of the OPO system actually correlates with *improved* performance acutely, and also allows CMS and Congress to better understand and address systemic problems through meaningful policy reform as necessary. CMS can take steps to change this culture by actively communicating to stakeholders how much they value stakeholder input and rely on whistleblower complaints.

8. Organ Discards

Questions addressed:

Are there additional requirements that CMS could implement that would improve the manner, effectiveness and timeliness of communication between OPOs, donor hospitals, and transplant programs?

Are there additional data, studies, and detailed information on why the current number of organ discards remains high, despite CMS' decision to eliminate the requirements for data submission, clinical experience, and outcome requirements for re-approval?

The industry as a whole has acknowledged that changes cannot be made solely to one part of the transplantation system. Similar to the outcome requirements that OPOs must meet, should CMS again consider additional metrics of performance in relation to the organ transplantation rate, considering that the number of organs discarded remains high? What should these metrics be?

Most often lost in conversations about organ discards - which often center both on transplant center risk aversion and, as research from alumni of the U.S. Digital Service has found, the deeply troubling variability in how OPOs manage the organ offer process - is that much of the problem results from UNOS's archaic and frictionful technology system over which organs are offered (in 2020, the House Appropriations Committee Report explicitly called for increased

competition for the OPTN contract as part the solution to organ discards, writing *"The Committee supports HHS's Request for Information for the technology system over which these organ offers are facilitated and encourages HHS to promote competition for this contract."*

In fact, UNOS's technology is so archaic that 17% of kidneys are offered to dead people, and investigating reporting from Kaiser Health News has found that *"a startling number of lifesaving organs are lost or delayed after being shipped on commercial flights, the delays often rendering them unusable"...* because UNOS *"typically track[s] [organs] with a primitive system of phone calls and paper manifests, with no GPS or other electronic tracking required."*

While we appreciate that, under the current structure, the decision to finally support patients and good governance by assigning the OPTN contract to competent, unconflicted contractors will ultimately lie with HRSA, it is still important for CMS to understand how the severe failures of the current contractor (UNOS) contribute to organ discards.

Additionally, it is important to note that recent, short-term increases in discards are actually a *positive* development, as they indicate that OPOs are responding to new, impending regulatory pressures to more aggressively recover organs from low-yield donors. This is evidence that CMS's correct decision not to credit OPOs for zero-donors is having its intended effect. In the past, OPOs routinely ignored many marginal organs; now, by appropriately pursuing more of them in patients' interests, there is a concomitant increase in discards, as OPOs offer more marginal organs than they have historically.

It is also important to note that researchers have little data to study with regard to how OPOs may have more or less effective ways to evaluate, procure, and allocate marginal organs. The difference between one OPOs discarded organ and anothers transplanted organ may be related to many factors that are important, but less visible parts of OPO practice, including: how the donor is managed pre-operatively, how the OPO practices allocation, and how the organs are (or are not) pumped, perfused, biopsied, or otherwise prepared and presented to centers as offers. Adherence to and quality of donor management goals vary widely between OPOs, and without an evidence basis to discern how OPO practices can optimize utilization, the root causes of discards can't be fully addressed.

In any case, the best way to inform iterative policymaking is for CMS to require full process data transparency from all OPOs, in line with already established international transparency standards, to best identify the differential practices across OPOs that lead to clinically similar organs being accepted or rejected at higher rates depending on the recovering OPO.

9. Variability in OPO Performance

Question addressed:

Once OPO performance on the outcome measures reaches this level, CMS will need to consider other factors that differentiate highly functioning OPOs from those that are less highly

functioning. We are interested in exploring what factors CMS may consider in this regard and ways to measure performance in these areas.

Given that, in the two years of OPO data CMS has published under the new OPO rule there has been a variability of as much as 470% between OPOs, this is a deeply important question. To best answer it, we believe there is an important reframing of the question to: *'why do some OPOs perform so stratospherically below the level of performance which peer OPOs have clearly demonstrated is possible?'* And, closely related: *how can this poor performance best be rectified?*

To fully answer the question of why some OPOs so dramatically fail, the best solution is for CMS to mandate full process reporting for OPOs, in line with international standards for procurement systems. This will enable meaningful, external data-driven research; apply oversight pressure, which has already been shown to correlate with the biggest relative improvements in OPO performance ever experienced; and actually help identify best practices for well-meaning OPOs who want to improve.

Even before the introduction of full process data transparency, however, we can already learn much from historical OPO turnarounds. The most relevant example to consider is that of the Indiana OPO, given that this was conducted in the context of peer-reviewed research.

In 2019, the Indiana OPO - amid oversight pressure from Indiana Senator Todd Young - brought in external consultants who spent just two days onsite reviewing the Indiana OPO's internal data and made recommendations for process improvements. Over the following 12 months, the OPO increased organ donation by 44%, with the key driver being that the OPO approached 57% more families.

This is extremely telling, for various reasons. Firstly, OPOs have a legal mandate to respond to every donation referral, so the very idea that the OPO had room to increase its referrals by 57% suggests a massive failure. Indeed, and related, whenever OPOs face media scrutiny for poor performance, the most common response is for the OPO to say that it plans to ramp up its hiring of front-line staff.

For example, see recent reporting on the failures of the OPO based in Minnesota, which is under investigation from the House Oversight Committee for "shocking mismanagement", responded that it plans to address its failures by "committ[ing] to expanding its staff" by adding least 20 people to its team in 2021 and plans to recruit more in 2022.". And earlier reporting on failures at the OPO based in New York City, which included internal documents outlining that its failures were often because the OPO "did not have staff to send" to respond to donation cases.

If even OPOs acknowledge that the root cause of their failure is often failure to staff appropriately, there is no reason to address that problem only sporadically and reactively once investigative journalism has unearthed it, especially given how difficult such reporting can be given the complete opacity OPOs have been afforded.

Perhaps even more tellingly, given that OPOs operate on a full cost-reimbursement basis, the failure to hire frontline staff (especially while executive salaries can exceed $1,000,000, entirely divorced from organizational performance) further underscores the need for OPO reimbursement reform with the goal of better incentivizing resource allocation decisions that drive organ recovery, rather than profligate spending on executive perks and self-enrichment (see oversight letter from Reps. Katie Porter and Karen Bass).

Additionally, it is important to consider that the improvement at the OPO came from *external* researchers accessing the OPO's data. That is to say, the Indiana OPO had this data all along, but apparently had neither the urgency nor the internal expertise to make use of it.

The OPO industry has grown from roughly $100 million annually to $3 billion over the last few decades, though little has changed about its practice. As the longest-serving OPO coordinator in the country wrote, *"I've watched the OPO industry stagnate and the outside world pass us by. It's hard to believe, but while surgeons perform medical marvels in the operating room, some OPOs still rely on fax machines for donation referrals and to share critical information. An industry frozen in amber. The government helped build the infrastructure of an industry from scratch, and then walked away for decades and let it atrophy."*

To make gains going forward, given that the needed expertise is often outside of the OPO industry, access to OPO process data must be democratized; no one should have faith that the OPO leaders who have failed for decades hold the insights to right their own ships; that said, we all should take comfort, however, in knowing how quickly OPOs actually can improve when given direction from unconflicted external experts as well as sustained pressure to adopt recommendations.

Given this, opening up OPO process data transparently is among the single most well-leveraged and sustainable solutions CMS can drive, given that this will enable consistent best practice identification and dissemination, as well as healthy pressures for OPOs to exert effort, shepard taxpayer dollars responsibly, and serve patient interests.

10. Patients' Rights

Question addressed: Did the transplant program provide you with information specific to your unique needs, medical situation, and potential transplant outcomes?

When my father and two of my aunts were on the waiting list for organ transplants, the single most useful information we could have received is how likely we were to receive a viable organ and on what timeline. Specifically, in the case of my father, we considered moving to another state to increase his chances of living. Similarly, I understand that some families face similar decisions regarding whether a family member should become a living donor versus wait for a deceased donor transplant.

Despite how vitally important this is, OPOs - the monopoly providers of lifesaving organ transplants - remain a complete blackbox for patients. CMS should move urgently to bring OPOs in line with international best practice standards for process data transparency.

As CMS wrote in the OPO Final Rule, *"The current OPO outcome measures are not sufficiently objective and transparent to ensure public trust in assessing OPO performance."* We agree completely, both regarding the previous metric specifically, as well as with the underlying premise that increased transparency into OPO performance is an important and necessary factor in ensuring public trust, which OPOs have repeatedly - and correctly - asserted is important to increasing donation rates.

CMS should build on this by providing the public with much greater transparency in OPO practice by bringing OPOs in line with establishing international standards for process data transparency.

Related, and even more acutely, patients deserve transparency around financial conflicts of interest for OPO executives. For example, and as expounded upon elsewhere in this RFI response, CMS does not require OPO executives and board members to disclose personal financial relationships with tissue processors or other partner entities, which can cause direct harms to donor families.

For example, LA Times investigative reporting into illicit and undisclosed financial relationships between OPOs and the "multibillion-dollar global business" found that donors families reported feeling that OPOs "misled them into agreeing to procurements." This marries with research finding that while 73 percent of families say it is "not acceptable for donated tissue to be bought and sold, for any purpose," only 18 percent of donor families report being told that their tissue donation might go to a for-profit company.

11. Organs for Research & Zero Donors

Questions addressed:

Data on organs submitted for research is self-reported by OPOs and there is currently no method to independently verify this information on a regular basis limiting utility in annual performance measures. Are there other methods CMS should consider that would be effective?

How can CMS implement an approach that both incentivizes OPOs and is not excessively burdensome through enforcement?

More recent data indicates that the number of "zero organ donors" is increasing significantly. A recent internal analysis indicates that "zero organ donors" increased by 31 percent between 2019 and 2020 (746 to 977) and 76 percent from 2017 through 2020 (555 to 977). In 2017, these donors represented 5 percent (555) of all deceased donors and 25 percent (1,215) of all discarded organs. In 2020, "zero organ donors" increased to 8 percent (977) of all deceased

donors and 31 percent (2,051) of all discarded organs. During the past decade, the rate of "zero organ donors" ranged from a low of 5.3 percent to a high of 8.5 percent in 2020 with an average annual rate of 6.0 percent.

We are interested in ways information on organ discard rates and organ acceptance practices can become more available and whether CMS should track and evaluate this information more closely and consider it for recertification purposes.

CMS is correct to seek comment regarding the inclusion of pancreata for research in the OPO metrics. The focus on the OPO rule is organs transplanted (not merely procured), which is a critical reform. However, the 2019 NPRM took a seemingly unintentional divergence from the 2006 rule, by interpreting Pancreatic Islet Cell Transplantation Act of 2004 which amended the PHSAto include all pancreata for research, instead of the narrower/more appropriate pancreata islet cells.

The main problem this creates is the ability - and incentive - for OPOs to game the system. Immediately after the OPO rule was first finalized, internal AOPO emails included OPO executives advising each other that *"Pancreas for research counts in both measures. If you have a donor with only a pancreas for research, that is an organ donor for the Donor Rate. Otherwise, a donor is any donor with at least 1 organ transplanted. Savvy (or cynical?) OPOs ought to start a pancreas for research program immediately."*

Given previous AOPO comments about how susceptible OPOs are to gaming metrics, this creates a major concern. Specifically, in 2013 AOPO wrote to OMB that perverse incentives in OPO regulations were "causing OPOs to 'game' the process of meeting the third standard by only targeting "high-yield" organ candidates" even though this practice was "in direct conflict with the mission of OPOs to pursue every viable organ for transplant to save even one life."

Indeed, this has already been borne out in the data, as pancreata recovered for research increased nearly 100% from 533 in 2020 (roughly equal to the 2019 and 2018 numbers) to 1,023 in 2021. In extreme cases, one OPO jumped from 1 research pancreas to 46 over that period, and another from 5 to 91, and analysis also shows how dramatically OPO tier rankings shift by removing research pancreases from the count.

This problem was pointed out in official comments from two high-performing OPOs (specifically, LifeSharing and Midwest Transplant Network) which highlighted how this loophole could be gamed and jeopardize the rule. This concern was borne out in a recent AOPO email chain with OPOs strategizing about how to exploit this loophole/game the new metric, as indicated above. Note: even occasional gaming the loophole could move an OPO from failing to passing. Limiting the count of pancreata for research to only islet cells procured for research is also much easier for CMS to verify and track, and will likely not be at such a significant volume as to impact OPO tier rankings.

For similar reasons, we also want to affirm our support for *not* giving OPOs credit for zero donors. While OPO objections to zero donors often anchored on myoptic view that, in any given single case, a transplant center can decline an organ through no fault of the OPO, CMS is correct to view this issue at an industry-level.

Navigating match runs to place organs at transplant centers is a common responsibility across all OPOs; over the course of an entire year, differential organ placement success rates indicate differential ability, processes, and effort at OPOs. If some OPOs are demonstrably worse than their peers at organ placement (which, again, is a core function of OPOs), then this constitutes a failure of that OPO. If the failure is significant enough to impact that OPOs tier ranking, then that OPO deserves to face regulatory consequence.

More plainly: over the course of an entire year, if any OPO has significantly higher discard rates than peers for clinically similar organs (absent a reasonable mitigating circumstance), then that OPO is costing patients their lives because of this critical failure.

Related, when considered this way, *not* crediting OPOs for zero donors is the best and only way to create regulatory incentives for all OPOs to improve their effort and processes in order for organ placement.

Conversely, crediting OPOs for zero donors will not only disincentivize OPOs from improving their organ allocation/waitlist navigating processes, but will remove all pressure from them to better manage their organ transportation couriers. After investigative reporting found that *"a startling number of lifesaving organs are lost or delayed after being shipped on commercial flights, the delays often rendering them unusable"* the industry lobbying narrative shifted to blame the couriers rather than to take any responsibility.

This framing, however, ignores that OPOs often hire low-end, unprofessional courier services and do not upgrade or professionalize their vendor-procurement processes, even after repeated issues, because those OPOs are not held accountable for these outcomes. And given that it is OPOs (and no other regulated stakeholder) that hires and manages courier services - as well as potentially investing in their own software logistics management platforms - this further underscores why CMS is correct, from a systems dynamics perspective, to *not* give OPOs credit for zero donors.

12. Tissue Banking Activity and Relationships with other Tissue Banking Organizations & OPO Reimbursement Reform

Questions address:

For OPOs that do have active tissue banks, how does this service impact or intersect with the OPOs primary mission of recovering and distributing organs?

We are soliciting comments on ways to: Increase the number of organs available for transplant for all solid organ types

Building on regulatory reforms recently finalized for OPO outcome measures, CMS can pursue additional reforms to OPO reimbursement structures in order to ensure that OPOs - which are currently the subject of two separate, ongoing, bipartisan investigations from the Senate Finance Committee and the House Committee on Oversight and Reform, including into OPO financial abuses - are incentivized to spend taxpayer resources toward the goal of organ donation.

Our research, in partnership with the Bridgespan Group, highlights that OPOs are funded on a cost-reimbursement basis, with Medicare and transplant centers covering 100 percent of costs for activities related to organ procurement, an arrangement which appears to be unique in US healthcare. In theory, this full-reimbursement model was created to ensure that OPOs always have incentives to recover organs. However, this has not always played out in practice, as OPOs, by their own admission, may choose not to pursue donors from whom only one or two organs are transplantable. Given that HHS's own data indicate that the majority of OPOs are failing in organ recovery efforts, it is clear that the current financial reimbursement structures are insufficient to incentivize productive resource allocation behaviors for OPOs.

OPOs are reimbursed based on self-reported costs—passing these costs along to the Centers for Medicare & Medicaid Services (CMS) and transplant centers—regardless of performance. The current OPO payment model does not give OPOs an incentive to reallocate resources in order to increase the number of organs available for transplant, and it reimburses OPOs for costs that may not, in fact, help produce the desired outcomes. This may have contributed to a historical increase in industry costs overall. An analysis of Medicare cost report data found that between 1996 and 2014, total costs for organ acquisition reported by US hospitals with at least one Medicare-certified transplant program increased by 253 percent, compared to the volume of transplants and donors increasing by just 45 percent and 57 percent, respectively. OPO organ acquisition revenues nationally total approximately $3 billion annually.

There are also special rules for kidneys, established due to the unique way Medicare covers end-stage renal disease. OPOs are guaranteed reimbursement for kidneys on the condition that they submit a cost report to detail their kidney procurement costs and calculate the related charge to Medicare, known as the standard acquisition charge (SAC). A 2020 paper on kidney costs published in the American Journal of Transplantation reported a range between $24,000 and $56,000 across different OPOs over a three-year period.

At the end of each fiscal year, if an OPO's kidney-recovery expenses exceed its total Medicare kidney reimbursements, Medicare will pay the difference via an additional payment—even if the OPO generates positive margins in other lines of business (e.g., tissue procurement, other organ categories) that could cover these costs. If the Medicare reimbursement exceeds the OPO's allowable kidney-recovery expenses, the OPO is required to repay Medicare the excess amount. While this attempts to drive cost neutrality, in practice kidney recoveries occur in

conjunction with recovery of other organs in a majority of cases, so it can be difficult to isolate the costs specific to kidneys, especially overhead and other operating expenses.

The 100 percent reimbursement for kidney costs creates incentives for cost-shifting, as OPOs have a financial interest in showing Medicare that their kidney-recovery costs exceed their reimbursements. Particularly for indirect costs (e.g., overhead, management), OPOs have the incentive to allocate as many costs as possible to kidney recovery rather than spreading them across multiple organ categories. This may impact the actual clinical practices of organ procurement, as some costs can be allocated to kidneys prior to recovery so long as there is an initial intent to procure one (even if those kidneys are not in fact suitable for donation).

For other organs, OPOs charge transplant centers a preset SAC, which is typically calculated based on the OPO's related costs and the number of organs procured in the previous year. SACs include both direct costs (e.g., operating room time) and indirect costs (e.g., management salaries, travel, marketing, and overhead). Indirect costs that might rightly be incurred by procurement of non-renal organs may in fact end up allocated to kidneys, driven by the practice of Medicare covering 100 percent of kidney procurement costs.

While transplant centers technically can negotiate SACs with OPOs, it is important to understand the context in which these negotiations occur. OPOs are geographic monopolies and subject only to limited financial disclosure requirements, leaving the transplant center with limited visibility into OPO costs and little negotiating power. As transplant centers have no other means under the law of acquiring organs, they are ultimately billed for organs at the discretion of the OPOs, experiencing price variation dependent on the macroeconomic environment as well as absorbing operating costs that OPOs have no structural pressures to contain.

The cost-reimbursement system means that OPOs can pass through all expenses to payors with little accountability and with limited incentive to allocate resources efficiently. In cases where a transplant center receives an organ from an OPO outside of its designated service area (DSA), it is responsible for paying the OPO's additional transportation costs, with minimal transparency into these costs or the extent to which they increase SAC fees.

There is also wide variability in SACs, both in the total amount and how they are calculated: kidney costs reportedly range between $24,000 and $56,000 across different OPOs, for example. As three OPO executives wrote in a 2015 paper on pancreas transplants ("The Economic Aspects of Pancreas Transplant: Why Is the Organ Acquisition Charge So High?"), "although often referred to as a 'standard acquisition charge' (SAC), it is better named an OAC [organ acquisition charge] as its components vary from organ to organ and from OPO to OPO. There is very little standard about it."

Inspector General audits, investigative reporting, and Congressional oversight have all documented OPOs spending taxpayer dollars profligately on activities unrelated to organ donation, including football tickets, private jets, lavish board retreats, and 5-star hotels. In recent years, some OPOs have established foundations to conduct a range of activities, including

those with expenses CMS does not consider allowable for OPOs under Medicare cost-reporting rules.

As Rep. Katie Porter noted in her 2019 letter to HHS regarding the OPO in her district: "According to the [Los Angeles OPO OneLegacy] foundation's most recently available tax filings, the foundation received $20–30 million in OPO funds in 2016. This money, rather than going to patients in need, now funds many of the same expenses that the OIG deemed impermissible, such as costs related to the Rose Bowl."

Because executive salaries can be allocated as indirect costs to per-organ cost-based reimbursements, a July 2020 oversight letter from Reps. Katie Porter and Karen Bass stressed the need for HHS to ensure that taxpayer dollars are not spent on overly generous compensation for board members or organization leadership. Currently, executive salaries do not correlate with whether an OPO is considered passing or failing according to new proposed OPO outcome measures.

In fact, tellingly, based on 2018 990 forms, the average compensation for the CEO of an OPO which HHS deemed as Tier 3 exceeded the average compensation for the CEO of an OPO in Tier 1; clearly, there is no correlation between compensation and performance, a symptom of the distorting effects of the 100% cost-reimbursement model on resource allocation decisions.

In addition to receiving SACs and Medicare reimbursements for organ recovery, OPOs are also compensated by tissue-processing partners (some of which are for-profit corporations) for procuring tissue, cornea, bone, and skin— recovering these from donors by virtue of their government monopoly status to recover organs. And while tissue recovery is not directly reimbursed by Medicare, in order to understand the financial incentives driving OPO behavior, it is important to consider the corrupting influence tissue revenue can have on OPO decision-making and resource allocation.

Unlike organ donation, which is overseen by CMS, tissue donation is governed by regulations within the Food and Drug Administration, although such oversight is confined to clinical regulation rather than financial or business practices. The Los Angeles Times found that tissue recovery is a "multibillion-dollar global business" and that "a single body can supply raw materials for products that sell for hundreds of thousands of dollars."

Unlike SACs for organs, prices for tissue and non-organ body parts are subject to market forces, meaning increased demand can increase prices and bring additional revenue for every incremental tissue recovery. Consequently, and as highlighted by our research with the Bridgespan Group and cited in a recent bipartisan oversight letter from the Senate Finance Committee, "OPOs have greater financial incentives to focus more on tissue recovery compared to their incentives to recover lifesaving organs."

Congressional investigations into OPO financial abuses have, thus far, identified two areas in particular where the severe lack of transparency around OPO finances has been most

egregiously abused: the accuracy and effectiveness of OPO cost reporting, and potential conflicts of interest related to tissue procurement.

For example, while OPO executives make decisions about dedicating resources to organ recovery versus tissue recovery, CMS does not require OPO executives and board members to disclose personal financial relationships with tissue processors or other partner entities. This lack of transparency around potential conflicts of interest regarding tissue may also affect the experience of donor families. Research shows that while 73 percent of families say it is "not acceptable for donated tissue to be bought and sold, for any purpose," only 18 percent of donor families report being told that their tissue donation might go to a for-profit company.

CMS can take concrete steps to align OPO financial incentives with the goal of maximizing transplants, ensuring patient safety, and enabling accountability. A payment system that increases transparency, standardizes reimbursements, and rewards OPOs for safely using every available organ in their given DSAs would be an important step toward achieving this goal. The most effective system is likely to be one in which financial incentives align with organ recovery and encourage OPOs to reallocate spending into investments that can safely and sensitively increase the volume of successfully procured lifesaving organs, such as frontline staff.

The ultimate goal of OPO financing reform is not to reduce costs, per se, but rather to increase the number of lifesaving organs available for transplant. Over the past several decades, the healthcare system as a whole has evolved from retrospective, cost-based reimbursement to prospective, fee-for-service reimbursement, and now toward value-based care, largely driven by reforms from CMS. For instance, from 1967 to 1984, Medicare employed a cost-based reimbursement system similar to the current OPO financing mechanism.

This led to significant inflation of hospital budgets, which was curtailed by adoption of a prospective payment system in which prices for certain bundles of services were defined upfront. OPO financing is now the only major area of healthcare that continues to be financed entirely on a cost-reimbursement basis. Both fee-for-service and value-based-care paradigms can provide valuable principles for OPO financing reform.

There are at least two non-statutory ways to implement reimbursement reform for organ procurement:

First, CMS can use its waiver authority under Section 1115A of the Social Security Act to design and launch a demonstration project (via the Center for Medicare & Medicaid Innovation) to test alternative methods of reimbursement. It has conducted similar demonstration projects in a variety of areas, such as the mandatory comprehensive joint replacement program which has successfully lowered costs. These mechanisms could be an effective way to pilot a new payment system for OPOs.

Second, CMS can change the current regulation governing payments to OPOs (42 CFR 413.200) by issuing a new regulation with a reformed financing mechanism that is fair and transparent and provides incentives to drive higher volumes of organ procurement, helping more patients access transplants.

In parallel to more paradigmatic reforms to OPO reimbursement systems, CMS should move swiftly to improve transparency of organ procurement costs. CMS currently provides instructions on cost reporting and a fee calculator (in Provider Resource Manual [PRM] 15-1, Chapter 31, or PRM 15-2, Chapter 33), and can issue new guidance on calculating SACs or enact new regulations to reform cost reporting to ensure the OPOs are allocating costs transparently and accurately.

Given that OPOs operate as monopolies, unlike other stakeholders in the field of transplantation, CMS should impose transparency requirements above and beyond those for transplant centers and donor hospitals, which are already subject to market pressures to contain costs and to otherwise allocate resources intelligently, responsibly, and with a focus on performance improvement.

One such potential cost-reporting reform would be to require OPOs to publicly report annual SACs by organ type for all organs, along with number of organs recovered and a detailed description of which costs are included in the fee and how they were allocated (potentially in the form of detailed financial statements that outline allocation of direct and indirect costs by line item). Additionally, CMS should require disclosures of financial relationships between OPOs/OPO leaders and partner entities (such as tissue processors and private jet service companies), or even prohibit OPO leaders from engaging in financial relationships with partner entities (as it does for Medicare-funded physicians under Stark Law).

In addition to being clearly in patient and taxpayer interests, such transparency is eminently reasonable. In fact, seven leading OPOs recently wrote to the House Committee on Oversight and Reform to commit to sharing them voluntarily, noting *"this is data which can be easily and readily shared by all OPOs, and, as suggested by Chairwoman Maloney, encourage our peers to join us in enabling sound, data-informed, pro-patient policymaking through such transparency."*

Adoption of these reforms could protect against instances of spending that have been the subject of a series of investigations and inquiries, and, most importantly, to align OPO resource allocation with the goal of maximizing organ donation.

13. OPO Technology/APIs, EHR Integration, and Organ Tracking

Questions addressed

Are there opportunities for OPOs to use electronic health record (EHR) application program interfaces (APIs) to facilitate key information transfer between the hospital and OPO?

Are there best practices regarding the arrangement of organ transportation between an OPO and a transplant program?

In 2021, alumni of the United States Digital Service performed a comprehensive analysis of OPO and OPTN technology and published a report endorsed by all 5 past, bipartisan HHS Chief Technology Officers. Key excerpts from that below are below, though we will first highlight key recommendations for CMS toward the goal of modernizing the deeply archaic organ donation technology ecosystem.

- CMS should consider any OPO's technological and logistics management capability in its criteria for competition for an OPO service area. Not only are such capabilities paramount for the management of any OPO DSA, but are of even greater importance to the extent an OPO might increase the size of the geography it covers and the workforce it manages. Specifically, CMS can define such capabilities as:
    - Ability to interface with Hospitals electronically using APIs
    - Ability to use automation and ML/AI to improve outcomes
    - Ability to respond in a timely manner to Reporting requirements.
    - Desire to innovate and improve Digital Services.
- CMS should support all HHS efforts to promote competition for the OPTN contract, including to separate the technology functions of the contract. UNOS's technology is demonstrably terrible (e.g., over UNOS's DonorNet system, 17% of kidneys are offered to deceased patients). This is not only a problem in and of itself, but UNOS's technology failings - including its refusal to meaningfully build and make available APIs to anyone but their cronies - rate-limits technology advancements across the entire transplant ecosystem.
- CMS should coordinate with the Office of the National Coordinator (ONC) to identify and address all barriers to building and implementing scalable platforms for integrating OPO technology systems with EMR, including to enable automated donor referrals.

Key excerpts from organ donation ecosystem technology report:

"Within the organ transplant community, people rely on various technical systems. For example, organ procurement organizations (OPOs) across the country each use one of 4 or 5 different programs, which are separate from additional programs used by transplant center staff. There is no key decision maker who controls all aspects of every system end-to-end, so we refer to the whole as the organ transplant ecosystem.

"There is one key tech system, however, known as the UNet℠ platform, through which most important data flows at some point. The UNet℠ system is closed and proprietary, so we were not able to view the coding architecture, but we discovered key insights through extensive user interviews.

"While investigating UNet℠ and the organ transplant ecosystem as a whole, we identified a number of shortcomings and opportunities.

- *"Technical Seams" Or Opportunities For User Error And Incorrect Data Entry*
  Technical seams are places between automated APIs, or computer-to-computer communication, where information tends to get lost or corrupted. When there are unnecessary, human-powered technical seams between computer systems, we create risk for lost or corrupted data.
- *Closed And Proprietary Systems Block Innovation*
  Under the current structure, the black box of UNet℠ provides no opportunity for collaboration or outside competition to drive innovation. In this context, the system owner (UNOS, whose funding results from a government monopoly contract) effectively keeps the United States government beholden to them as contractors with their proprietary tech, against the best interests of taxpayers, physicians, and patients.
- *Siloed Systems Prevent Thorough Data Analysis*
  The current "transplant tech ecosystem" contains many disparate systems that each handle their own data. In systems where there are numerous stakeholders, whoever speaks the loudest often gets to determine the next feature built. In more mature technical organizations, to overcome this human political bias, all decisions on what to build next are validated with central data to ensure the expected outcome is achievable.
- *Too Much Focus On "Feature Releases" Instead Of Iterations*
  Users we talked to described upgrades specifically on UNet℠ as patch fixes. They described frequent "feature releases," built up with PR campaigns that illustrate the lack of a more modernized approach. The more modern approach, iterative development, involves small changes to a small subset of users. When those changes are effective, then a wider release occurs.
- *Lost Organs From Transportation Issues & Lack Of Tracking*
  Hundreds of recovered organs have not been transplanted because they were lost or damaged in transit. With the vast improvements in logistics and transportation within the private sector, organs should not be getting lost this way.

"We have recommendations from both a top-down and bottom-up approach to fix the current technological systems to make organ donation, matching, and transportation processes more efficient.

"<u>Top-Down (Long-term change)</u>
By "top-down" change, we envision federal contracting reform for the OPTN, especially to create more competition and attract a larger, more dynamic, pool of bidders. This process will take time, at least 1–2 years before any new vendor(s) will begin to release technical changes in the system. Under this approach, we recommend the following:

- *Restructure contracts to focus on pieces of discrete domain business logic (see Strategy for Buying OPTN Tech).*
- *Ensure future OPTN contractors use open-sourced, cloud-based technology from a government approved cloud provider.*
- *Ensure future OPTN contractors adopt modern digital strategy techniques, including iterative development.*
- *Create or require a central data warehouse under an OPTN caretaker that enables data-driven decision making, with standardized metrics.*
- *Ensure future OPTN contractor(s) are incentivised to engage public-private partnerships to improve patient outcomes.*

"Bottom-Up (Short-term change)
In the "bottom-up" approach, we see startup innovators working in the present ecosystem to move the field forward. This approach depends on whether UNOS begins to work with new startup technologies — which they currently have no incentive to do — and necessitates the following steps:

- *Allow third-party innovators to create more effective software that meets the needs of OPOs.*
- *Require UNOS to create robust application programming interfaces (APIs) that are accessible to a larger group of users.*
- *Instruct OPTN, who owns the data that UNOS has control over, to require UNOS to share data access with third-party innovators who are bringing solutions to the organ transplant ecosystem via the private sector.*
- *UNOS shall be instructed to provide said data at no cost to the qualified third party innovators as this data has been collected, maintained, and paid for under the current contract with OPTN (U.S. Government).*

"UNOS Tech is a Blackbox
From the start it is important to note that UNOS considers the tech "internals" of their system closed and proprietary. We acknowledge their right to treat their technology as proprietary, but we feel strongly that this decision goes against modern day best tech practices. We also feel concerned that by keeping their system proprietary, UNOS is exploiting their position of privilege bestowed by the U.S. Government in a way that blocks outside competition. Without directly working for UNOS and navigating any Non Disclosure Agreements (NDAs), which appear to bar any public disclosures, there is no clear way to know how they architect and build their systems. While it is common for software providers to create proprietary tech platforms, an opaque entity at the center of the organ transplant ecosystem has the effect of stifling innovation and preventing the field from benefiting from advancements happening in the rest of the tech and healthcare industries. It allows UNOS to unilaterally determine what acceptable organ transplant technology looks like.

"Organ Procurement Organization (OPO) Tech

OPO technology varies greatly between each organization, but ultimately they all employ various digital and analog processes for overcoming shortcomings that flow down from the UNOS UNet℠ foundational system. We note that the primary technical systems utilized by OPOs for managing cases are privately owned and operated. While there are at least five separate technical systems procured and utilized by OPOs, we chose to highlight and discuss the dominant system in the community, Transplant Connect's iTransplant℠ software.

"All the other systems suffer from similar shortcomings, leaving many users frustrated with the amount of work and training required to constantly shift between several technical systems to perform basic functions. As an example of how this surfaces, when a transplant center has to make a decision on an organ offer they have to look at multiple screens: the donor info in DonorNet, the candidate ranking info in Waitlist, and then candidate's clinical info in the transplant hospital's EMR. It would be much easier and quicker if they could look at one screen for this info to make the offer decision.

"Technical Seams Can Lead to User Error & Corrupt Data
Technical seams are the places between automated APIs, computer-to-computer communication, where information tends to get lost or corrupted. In the early days of computer software, it was very common for data to get lost or corrupted when it was manually transferred from a physical paper form onto a computer. Over time, those forms transitioned completely onto a computer and the challenge became getting the relevant data securely from one computer system to another. Computers perform this task of transferring data with much higher reliability than any human could achieve.

"When there are unnecessary, human-powered technical seams between computer systems, we create risk for lost or corrupted data. We require heavier than necessary processes where multiple users must log into a system to verify that mistakes were not made, and that all systems have matching data. An example of this in the organ transplant ecosystem is that often OPO coordinators will enter data for labs, then a lab technician will also log in to verify the data matches. This points to the urgency of getting things right, since a simple user mistake could mean a lost opportunity for a transplant, or a catastrophic, fatal event for a patient who receives the wrong organ.

"Closed and Proprietary Systems Block Innovation
"Under the current structure, the black box of UNOS UNet℠ provides no opportunity for outside competition to drive innovation. It is important to understand why open source principles create transparency and trust. Additionally, the government should do proper-risk assessment to determine the place for transparency and open source technology, and where opacity is crucial to the delivery of services.

- *By relying on code that exists in the public domain, the organ transplant ecosystem benefits from millions of coders who are constantly improving the quality and security of the software.*

- *If the core software is Open Sourced, the current tech provider is incentivized continuously to deliver a higher quality product or risk a competitor improving on the publicly available code base.*
- *If the government must transition the software, utilizing Open Source libraries increases the likelihood that incoming technologists can understand and familiarize themselves with the code.*
- *Open source software does not mean underlying data generated by a system is public, only the code powering the servers. The servers themselves with patient data are highly secured and protected.*

See Building and Reusing Open Source Tools for Government

"Siloed Systems Prevent Thorough Data Analysis
The current organ transplant ecosystem contains many disparate systems that each handle their own data. A better solution would be to build a Data Warehouse as a Single Source of Truth (SSoT) with the OPTN technical system caretaker. Data Warehousing technology has evolved rapidly over the last decade, and has become commonplace in the tech community to host massive datasets in near real-time.

"Creating a SSoT goes beyond just consolidating data and making life easier for end users to consume data. Modern tech teams require these SSoTs to drive decision making on which development task(s) should be addressed next. In systems where there are numerous stakeholders, whoever speaks the loudest often gets to determine the next feature built. In more mature technical organizations, to overcome this human political bias, all decisions on what to build next are validated with data to ensure the expected outcome is achievable.

"By embracing data driven decision making, product management teams pore through all available data, make hypotheses about what they expect to happen if a change occurs, then model it to see if it is likely to occur. For example, if a certain web page for entering organ data is often skipped, that data should be available and analyzed to question why this is occuring. After asking users, the team can make changes to eliminate or improve that page. This is a simple example involving a web interface, but, with access to all available organ data, there would be increased opportunities to analyze all systems and make determinations around why certain actions lead to certain outcomes, with a focus on improving the ecosystem as a whole with every decision.

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"OPO Tech is Primed for Innovation
While it creates huge variance and inconsistency, one of the advantages of having numerous OPOs is that they create competition through their choice in what system they use. This competitive marketplace creates the possibility for private investment and other efforts to move faster than the U.S. government. Currently, OPOs have a patchwork of systems to collect data, manually update UNOS UNet℠, and contact relevant parties, often through numerous phone calls that are not tracked nor documented. There is a strong possibility that, by compelling UNOS UNet℠ to open up APIs, a startup vendor could move toward technological consolidation of all these processes.

"Currently, it is difficult for any startup company to develop software knowing that they won't have access to relevant data piped directly into their systems. This makes it especially burdensome for the OPO to transition to a new system and manually re-enter all relevant data.

"In order for this innovation to occur, we strongly encourage the government entity overseeing the OPTN contract, which is currently HRSA, to direct UNOS UNet℠ to prioritize enabling third party software development by requiring UNOS to create robust APIs accessible to a larger group of users. This would allow third party innovators to create more effective software that meets the needs of OPOs.

"Lost Organs from Transportation Issues & Lack of Tracking
"A recent study found that hundreds of organs could not be transplanted because of transportation problems. We live in a world where it's rare to order an item from an online vendor and not have the ability to track its location in real time with complete confidence in its arrival, which makes an organ lost on its way to a life-saving operation especially shocking.

"Modern logistics problems have already been solved by numerous industries. Organ transportation may be unique in some ways due to the sensitive handling required, but there are

industry experts in the form of startups willing to invest heavily in tackling the technology and logistics challenges involved in moving organs. These startups could not only bring the likelihood of losing an organ down to 0%, but could also attach hardware used to track data like temperature, vibration and other relevant data during transit. This valuable logistical and monitoring data, with machine learning applied, results in the standardization of best practices for the movement of every organ in the ecosystem as well as eliminating the outliers. Monitoring and systematizing these factors could help improve patient outcomes post-transplant, and increase patient survival rates by years.

"What's blocking these innovators from competing is that there is no strong force to compel foundational systems, such as UNOS's, to share the data required to support a logistical platform to monitor and to move organs. The organ transplant ecosystem should continue to welcome and support those willing to make a positive impact in the community as a whole.

"An emerging tech business trying to enter the complex organ transplant ecosystem faces an uphill battle. UNOS and OPOs act as full-service operations and tend to view these startups as competition rather than partners."

Respectfully submitted,

Greg Segal, Founder & CEO
Organize